K013897/S1

January 15, 2002

MAY 21 2002

Bio-Scan
See life in real-time

SUMMARY of SAFETY and EFFECTIVENESS

I. GENERAL INFORMATION PER 21 CFR 807.87

Device Classification Name:	Solid State X-Ray Imager (flat panel/digital imager)
510(k) Submission Type:	New Device
Regulation Number:	892.1650
510(k) Number:	K013897 filed on November 26, 2001
Device Names:	***IRIS 20, IRIS 41, IRIS-View***
Device Product Code	90 MQB
Device Classification:	Class II, per *FDA guidance for the submission of 510(k)'s for Solid State Imaging Devices*, FDA, CDRH, ODE issue date August 6, 1999
Predicate Device:	Generic X-Ray film/screen (a preamendment device)
Registration Action:	Device Listing Document Number 103059 for ***IRIS*** Device Models submitted to FDA, CDRH, Information Processing and Office Automation Branch (HFZ-308) was filed on 07/24/2001
Applicant:	***Bio-Scan SA***
Manufacturer's Address:	Bio-scan SA, Pre Bouview 27, CH-1217 Meyrin/Geneva, Switzerland
United States Contact:	Richard M. Sano Consultant to Bio-Scan SA 153 Sanford Lane, Stamford, Connecticut 06905 Phone: 212-305-1831 Page Number: 917-424-0330 FAX: 203-323-3329 E-mail: rsano50390@aol.com
Proposed Labeling:	Operators Manual, Preliminary Product Data Sheets, CE, ISO, and EN Labels are included in the abbreviated 510(k) submission

II. DEVICE DESCRIPTION

IRIS SOLID STATE X-RAY IMAGER
RECTANGULAR SSXI FLAT PANEL X-RAY TRANSDUCER
Applicable elements contained in *FDA guidance for the submission of 510(k) 's for Solid State Imaging Devices*, FDA, CDRH, ODE issue date August 6, 1999

Indications for Use.

Models **IRIS 20** or **IRIS 41** SSXI detector combined with **IRIS-View** Image Acquisition control, display viewing, and archiving console is indicated for use as a SSXI Portal Imaging Device used in conjunction with Medical Accelerator Radiotherapy Devices as an alternative to Conventional Portal Film.

Detectors

The **IRIS** flat panel X-ray detector is available in two sizes, 20 x 20 cm (**IRIS 20**) and 41 x 41 cm (**IRIS 41**), with an Element Matrix of 256 x 256 and 1024 x 1024 respectively. X-rays are converted to light using a $Gd_2O_2S(Tb)$ opto-mechanical luminescent screen coupled to an Amorphous Silicon Thin Film Transistor Photodiode Integrating Storage Matrix Array.

Viewing Console

The **IRIS-View** console accepts the digital signals from the detectors through a PC card interface into a standard PC with a Microsoft Windows operating system. Software processing of the data is applied to enhance the visibility of the viewed image seen on a standard PC Color Monitor.

III. REGULATORY REQUIREMENTS

Under MDA, the **IRIS** Device in this abbreviated 510(k) submission is being shown to be substantially equivalent to a legally marketed predicate device, Generic X-ray film/screen (a preamendment device). Even though the preamendment device is exempt from 510(k) requirements, *FDA guidance for the submission of 510(k) 's for Solid State Imaging Devices*, FDA, CDRH, ODE issue date August 6, 1999, assigns a classification of Class II and a Product Code "90 MQB" for these SSXI devices.

IV. NONCLINICAL CONSIDERATIONS

A. Physical Characteristics:

1. Overall Dimension: **IRIS 20**, 26 x 53 x 7 cm, **IRIS 41**, 69.2 x 59.9 x 5 cm
2. Active Area: **IRIS 20**, 192 x 192 mm, **IRIS 41** 409.6 x 409.6mm
3. Matrix : **IRIS 20**, 256 x 256 (750 x 750µm), **IRIS 41**, 1024 x 1024 (400 x 400µm)
4. Fill Factor: 80%
5. Drawings: Cutaway of the SSXI panel, System Components and Connections
6. Power: 110vac ±10% 60 cycle or 230vac ±10% 50 cycle

B. Operational Functions:

1. Exposure Characteristics: There is no physical or electrical control of the Medical Accelerator possible through any manual or automatic **IRIS** or **IRIS-View** control interactions. The Medical Accelerator which is used with **IRIS** is not manufactured or marketed by ***Bio-Scan SA***. When used in conjunction with a Medical Accelerator, the **IRIS** device is as passive as X-ray film, and does not control output of Energy from the Medical Accelerator Device.

   Frame rate: Typically single static images, **IRIS** is not intended for fluoroscopic applications

   Dynamic Mode: dependent on field of view, from 10 fps for 10 x 10cm partial area to 4 fps for 41 x 41cm

   Integration time: 285mecs to 10,000msec (user selected)

2. X-ray Absorber: 25mm thick aluminum absorber

   Detection properties: Up to 30 MeV accelerator beam source
   Measured linear from 50kV to 117kV

3. Energy Conversion: $Gd_2O_2S(Tb)$ opto-mechanical luminescent screen

4. Readout Mechanism: Amorphous Silicon Thin Film Transistor Photodiode Integrating Storage Matrix Array, 35μs signal charge transfer time, minimum integration time 285msec

5. Output Signal: Internal between SSXI Detector and **IRIS-View** PC Computer is 16 bit intensity data and serial matrix addressing output signal for images into a network or onto CD-R or CD-RW are DICOM III standard format. (Bitmap format is also available for standard PC graphic presentation archiving)

C. Functional Characteristics:

1. No video Signal output, Output to Monitor is SVGA PC display standard
2. DQE: over 65% at 0.3 mm^{-1} frequency for 10μGy exposure
3. SNR: proportional to square root of exposure, SNR vs. Entrance Kerma is measured and graph submitted from 0 to 25 μGy for 50kV to 117kV showing SNR from 25 to 275
4. MTF: measured and graph submitted from 0.1 to 1.275mm^{-1} frequency showing MTF from 0.98 to 0.01
5. Aliasing: Matrix doubling algorithm is utilized to eliminate aliasing
6. Dynamic Range: Slice Profile of a 45° wedge filter image shows input energy from 18MeV vs. 16 bit digital intensity output. Dose Response is plotted from 0 μGy to 40 μGy for 50 to 117 kV, showing linear response from 0 to 65,535 intensity units.
7. Lag Time: Lag time includes 35μsec signal charge transfer and reset to zero
8. Underscanning: Field of View is user selected from the **IRIS-View** Console

9. X-ray Beam Alignment: Equipment installation function, Detector is mounted in alignment directly behind X-ray film cassette housing on the Medical Linear Accelerator Arm.
10. Pixel Defects: up to 5% may be noisy or inefficient and are ignored by a calibration protocol. These defects are corrected by adjacent pixel averaging algorithm
11. Device Ready: After one hour after power turn-on, **IRIS** Device is "Ready" and after an exposure in 280 msec the **IRIS** Device can acquire another image.
12. Latent image: Part of the readout cycle is the reset to zero. After 35μsec, the integrator is reset to zero with in a few milliseconds. A time of 280 msec total is set before a new integration

D. Exposure Characteristics:

1. Dose Requirement: Acceptable SNR or 100 can be achieved at Entrance Air Kerma of 2μGy from 50 to 117kV
2. Stability: After one hour of power on, the IRIS system is stable.
3. Uniformity: Weekly Quality assurance protocol produces a calibration matrix, which corrects for any non uniformity of the gain of individual pixels and also corrects for X-Ray beam non uniformities.
4. Frame Rate: This device is not indicated for Fluoroscopic applications.
5. Reuse Rate: Serial static images can be acquired from 4 fps to 10 fps depending on field of view selected. The limitation is related to readout rate from the photosensors.

V. SAFETY

A. Ready Indicator: An indicator with the word "READY" is seen on the monitor when the system is prepared to accept and process an X-ray input.

B. Passive System: The **IRIS** detector is passive as is x-ray film, and does not control the x-ray beam or movements of the Therapy accelerator. Bio-Scan does not manufacturer or distribute the Medical Accelerator Therapy devices.

C. Leakage Currents: The detector is mounted under the treatment table and not in contact with the patient. However, as with UL testing, conformity with all provisions of the directive 93/42/EEC certifies through testing by an authorized body that the system passes ISO 13485/EN46001 Quality system for medical devices.

D. RF Emissions: The FCC Class A Verification testing by an authorized body was performed to assure that EMC emissions are within levels that do not interfere with other devices.

VI. CLINICAL CONSIDERATIONS - EFFECTIVENESS

A. Concurrence Effectiveness Study: A clinical trial under Local IRB approval was sponsored and conducted by University of Pennsylvania Radiation Oncology Department, Division of Medical Physics with 30 patients scheduled to undergo radiation therapy. A table of reader responses was developed comparing the results from x-ray film with simultaneously acquired **IRIS** SSXI Images. Reading was done by specialists in the radiation treatment of the specific target organ lesions to be irradiated.

B. Effectiveness Results:

1. In no situation was any quality of the Bio-Scan Image rated of poorer quality than the X-ray film image
2. In 27 out of 30 comparison images, the Bio-Scan Images were rated better than the X-ray images
3. In three out of the total of 30 image comparisons by 7 physicians, the rating was considered equivalent

C. Effectiveness Conclusion: Physicians with expertise in the Speciality of Radiation Oncology for the target organ, rated the ***Bio-Scan*** **IRIS** results better in 90% of the comparison images or equivalent in 10% of the studies to the practice standard used, X-ray film/screen cassette acquired images.

D. Sample Images: Copies of all 60 comparative images are printed in the submission and samples of films are provided in the submission. Copies of the **IRIS** images are provided in CD for review as bitmap images.

E. Other findings: Written comments by Oncology readers of the comparative images

1. "Windowing (on **IRIS-View**) allows much more dynamic range so that each aspect of the assessment can be individually optimized."
2. "Increased dynamic range (of **IRIS**) helps assessment"
3. "Table edge interferes with assessment of both modalities (**IRIS** and film)."
4. "Film assessment is very difficult. Very simple with **IRIS**."
5. "Study is good, but technique not as good as other films (study # 9010)."

VII. LABELING

Indication for use, promotional PowerPoint presentation, promotional product data sheets, user manual, installation instructions, and scientific papers (bibliography) are provided in this submission.

VIII. QUALITY ASSURANCE PROGRAM

The ISO 9001 "Quality Documentation including the CE 0120 "Quality Manual Master File" is available on-site for inspection. Upon request, a copy can be made and submitted for review by FDA ODE.

The declaration of Conformity is included in the submission per directive 93/42 CE:

❑ ISO 9001	Quality system
❑ ISO 13585/EN 46001	Quality system, medical devices
❑ EN 1441	Risk Analysis
❑ EN1041	Information supplied by the manufacturer with medical devices
❑ CEI 61223-3-1	Evaluation & routine testing in
❑ CEI 61 223-3-3	medical imaging departments
❑ EN 980	Graphical Symbol for use in the labeling of medical devices
❑ EN 540	Clinical investigation of medical devices for human subjects
❑ EN 60601	Electromagnetic Compatibility (FCC Class A)
❑ EN 60950-A4	Safety on information technology equipment

The Testing was done by: SGS Yarsley International Certification Services Ltd as Notified Body CE 0120

INTERTest Systems, GMBH, international Zulassungen und Testsysteme

Copies of the Certificates of Compliance are included in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Bio-Scan, SA
% Mr. Richard M. Sano
Consultant
Columbia University
The Neurological Institute
Mail Box #48
710 West 168th Street
NEW YORK NY 10032

Re: K013897
Trade/Device Name: Solid State X-Ray Imaging System (IRIS) Model 20 & 41
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MQB and 90 LNH (Accessory)
Dated: February 16, 2002
Received: February 20, 2002

Dear Mr. Sano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013897

Device Name: **IRIS 20 and 41 with IRIS-View**

Indications For Use: **Models IRIS 20 or IRIS 41 SSXI detector combined with IRIS-View image acquisition control, display viewing, and archiving console is indicated for use as a SSXI Portal Imaging Device used in conjunction with Medical Accelerator Radiotherapy Devices as an alternative to Conventional Portal Film.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013897/S1